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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/469,530 12/22/99 DAMPEIROU

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020311 HM22/0301
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EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 03/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)
	09/469,530	DAMPEIROU ET AL.
	Examiner Alycia Berman	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 November 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of the preliminary amendment filed December 22, 1999 and the Declaration filed May 30, 2000. Claims 1-19 are pending.

Specification

2. Applicant is reminded of the proper content of an abstract of the disclosure. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.
3. The abstract of the disclosure is objected to because of the term "new" in line 3. Correction is required. See MPEP § 608.01(b).
4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
5. The disclosure is objected to because of the following informalities: the amounts of components in the examples are given using commas instead of decimal points. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acrylic copolymers and polyethylene

glycol/polypropylene glycol copolymers, chitin, Tweens and Spans, ethoxydiglycol and hydrolyzed wheat gluten, respectively, does not reasonably provide enablement for an adhesive agent, a thickening agent, surfactants, solvents and a binding agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Not all of the components would be expected to behave the same. Therefore, there would be no reasonable expectation of success by using any possible adhesive agent, thickening agent, surfactant, solvent or binding agent. One skilled in the art would not be enabled to determine which adhesive agent, thickening agent, surfactant, solvent or binding agent is suitable in the compositions without undue experimentation.

8. Claims 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a dosage range of 3 to 85% of phytohormonal extracts and a dosage range of 10 to 40% by weight of a thickening agent, respectively, does not reasonably provide enablement for a content in phytohormonal extracts ranging from 3 to 85% or a content in thickening agent ranging from 0.75 to 40% by weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification discloses at page 4, lines 28-30 that the preparations contain phytohormonal extracts at a dosage ranging from 3 to 85% and the thickening agent at a dosage range from 10 to 40%. A dosage range is different from a

concentration or quantity of a component in a composition. Additionally, the specification does not disclose any range of thickening agent less than 10%.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1 is indefinite because it recites "characterized in that they include" in line 3. It is unclear if the plant extracts are merely examples of the types of compositions that are being claimed or if they are required limitations of the claims.

12. Claims 1-3 are indefinite because they recite the term "new" in line 1 of each claim. This type of terminology is improper in claims. Deletion of the term is required.

13. The phrases "high viscosity" and "viscous excipient" in claim 1 are relative phrases that render the claim indefinite. The terms "high viscosity" and "viscous excipient" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Neither the claim nor the specification provide any limits as to what is considered a high viscosity or viscous. Anything that flows is viscous and any viscosity could be considered high when compared to something of a lower viscosity.

14. Claims 1 and 3 are indefinite because they recite "estrogen type action". Applicants' intent is unclear as to what is encompassed by estrogen **type** action.

Amendment of the claims to read "estrogenic activity," for example, would overcome this rejection.

15. Claim 1 is indefinite because it is unclear if "*pinnata*" is a species of *Kigelia* or if it is from another genera. Amendment of the claim to read "*Kigelia africana* or *Kigelia pinnata*" would overcome this rejection.

16. The recitation "like those of the transdermic device type" in claim 2 renders the claim indefinite. It is unclear how an adhesive porous dressing is like a transdermic device. It is also unclear what is encompassed by a transdermic device type.

17. Claim 2 is indefinite because it is unclear what is encompassed by "an adhesive porous dressing". Is Applicants' intent to claim an adhesive composition in the form of a cream, ointment, lotion, etc. or to claim an adhesive bandage type product? Clarification is requested.

18. Claims 3 and 4 are unclear because they recite common names of plants but does not provide the genus and species. Common plant names are indefinite because many different types of plants may have similar common names. It is requested that Applicant supply the genus and species of each plant claimed.

19. The term "pasty" in claim 12 is a relative term that renders the claim indefinite. The term "pasty" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What is a "pasty" preparation?

20. Claim 15 recites the limitation "the content in phytormonal extracts" in lines 1-2. Claim 17 recites the limitation "the content in thickening agent" in lines 1-2. Claim 18 recites the limitation "the content of solvent" in lines 1-2. Claim 19 recites the limitation "the content of flavosterone" in lines 1-2. There is insufficient antecedent basis for these limitations in the claims.

21. Claims 15, 16, 18 and 19 are indefinite because they recite percents without units. Are the percents by weight, volume, mass, etc.?

22. This application is replete with 35 U.S.C. 112 issues. The above are just some examples. Applicant is required to review all of the claims for 35 U.S.C. 112 issues and make appropriate corrections.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1-3 and 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Huffstutler, Jr. et al. (US 5,466,455).

Huffstutler teaches that plant extracts are useful in topical cosmetic compositions for their therapeutic benefits. For extracts of *Glycrrhizae radix* (licorice), *Kigelia pinnata* and *Salvia officianalis* (sage), *inter alia* see column 3, line 45 to column 4, line 36, especially lines 8, 9-10 and 21, and claim 1. For gels, creams and ointments, see

column 5, lines 39 to 41, column 6, lines 14 to 17 and column 11, lines 24 to 29. For adhesives and porous dressings, see column 5, lines 44 to 46, column 6, lines 21 to 23 and column 14, lines 9 to 35. For preservatives, see column 10, lines 42 to 44. For surfactant, see glyceryl monostearate in Example B2, column 11, line 55 and polysorbate 80 in Example B4, column 12, line 39, for example. For solvent, see column 11, lines 27 to 29 where the extract is dissolved into a carrier solution. As admitted by Applicant at page 4, lines 17-19, the adhesives can also act as thickeners and *vice versa*. Additionally, the adhesives are considered binding agents.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

27. Claims 1-3 and 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huffstutler, Jr. et al.

Huffstutler teaches all the limitations of the claims as stated above. It does not teach the Kigelia extract in a solution of water and butylene glycol or the percents of phytohormonal extract, Kigelia extract, thickener, solvent or flavosterone.

Huffstutler does disclose at column 8, line 39 that the extraction is carried out with water, C₁-C₁₀ alcohols and solutions of these. Butylene glycol, an alcohol containing four carbon atoms, is a known solvent as evidence by Hawley, G.G., 'The Condensed Chemical Dictionary', 10th Ed., Van Nostrand Reinhold Company, New York, 1981, page 164. It is considered within the skill in the art to select suitable solvent solutions from among those known in the art for use with the plant extracts. It is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). Therefore, absent evidence of unexpected results, the specific solvent system for the plant extracts and the percents of components do not render the claims patentable over the prior art. It is the Examiner's position that any one of the plant extracts exhibiting estrogenic activity inherently contains flavosterones. Burden is shifted to Applicant to show that none of the plant extracts disclosed by Huffstutler contain flavosterones as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of Huffstutler using any known solution and

selecting optimal parameters with the reasonable expectation of obtaining a therapeutic composition.

28. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huffstutler, Jr. et al. as applied to claims 1-3 and 6-19 above, and further in view of Kelly (US 5,830,887).

Huffstutler discloses all the limitations of the claims as stated above. Huffstutler does not teach an extract of soya.

Kelly teaches that extracts of soya that contain phyto-oestrogens (estrogenic type action) are useful in topical compositions such as ointments, creams, pastes and gel, *inter alia*. See, for example, column 6, lines 23 to 26 and column 9, lines 49 to 59. Kelly also discloses that any legume plant such as Indian licorice (*Abrus precatorius*) and clover (*Trifolium pratense* and *T. subterranean*) are suitable sources of extracts containing phyto-oestrogens (col. 7, lines 19-22 and 35 and col. 8, lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of Huffstutler and add soya extract as taught by Kelly with the reasonable expectation of obtaining topical compositions with estrogenic activity.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cariel (US 4,054,649) discloses *Alchemilla* extract (Common Lady's mantle) in topical compositions. Sharaf discloses the estrogenic activity of

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extracts of *Glycyrrhiza* (licorice) and *Trifolium* (clover). Anguelakova et al. disclose the estrogenic activity of extracts of hops. Kopcewicz discloses the estrogenic activity of extracts of sage. Binutu et al. disclose the antibacterial and antifungal properties of *Kigelia pinnata*.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4456 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
February 23, 2001


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